

What is claimed is:

1. An immunogenic composition comprising:

a recombinant Bacille Calmette-Guerin (rBCG) having a first extrachromosomal nucleic acid sequence comprising a gene encoding for a first Mycobacteria major extracellular protein selected from the group consisting of 30 kDa protein, 23.5 kDa protein, 32 kDa protein and combinations thereof, and a second extrachromosomal nucleic acid sequence comprising a gene encoding for a second Mycobacteria major extracellular protein selected from the group consisting of 30 kDa, protein 23.5 kDa protein, 32 kDa protein and combinations thereof,

wherein said Mycobacteria major extracellular proteins are over expressed and secreted.

2. The immunogenic composition according to claim 1 wherein said first extrachromosomal nucleic acid sequence is under the control of a promoter that is not a heat shock promoter or a stress protein promoter.

3. The immunogenic composition according to claim 1 wherein said second extrachromosomal nucleic acid sequence is under the control of a promoter that is not a heat shock promoter or a stress protein promoter.

4. The immunogenic composition according to claim 1 wherein said first and said second extrachromosomal nucleic acid sequence are under the control of a promoter that is not a heat shock promoter or a stress protein promoter.

5. The immunogenic composition according to claim 1 wherein at least one of said major extracellular proteins are non-fusion proteins.

6. The immunogenic compositions according to any one of claims 1-5 wherein said first or said second Mycobacteria major extracellular protein is from a species of *Mycobacterium* selected from the group consisting of *Mycobacterium tuberculosis* (Mtb), *Mycobacterium bovis* (MB), and *Mycobacterium leprae* (ML).

7. The immunogenic composition according to claim 6 wherein said first or said second Mycobacteria major extracellular protein is selected from the group consisting of Mtb 23.5 kDa protein, Mtb 30 kDa protein, Mtb 32A kDa protein, MB 30 kDa protein, MB 32A kDa protein, ML 23.5 kDa protein, ML 30 kDa protein and ML 32A kDa protein.

8. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is Mtb 23.5 kDa protein.

9. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is Mtb 30 kDa protein.

10. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is Mtb 32A kDa protein.

11. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is MB 30 kDa protein.

12. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is MB 32A kDa protein.

13. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is ML 23.5 kDa protein.

14. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is ML 30 kDa protein.

15. The immunogenic composition according to claim 7 wherein said first or said second Mycobacteria major extracellular protein is ML 32A kDa protein.

16. The immunogenic compositions according to any one of claims 1-5 wherein said extracellular non-fusion proteins are over expressed and secreted such that a protective immune response is induced in a host.

17. The immunogenic compositions according to any one of claims 1-5 wherein said immunogenic composition is recombinant Bacille Calmette-Guérin (rBCG) and is growth regulatable.

18. The immunogenic composition according to claim 17 wherein said growth regulatable rBCG is selected from the group consisting of prototrophs, auxotrophs and metabolically impaired mutants and combinations thereof.

19. The immunogenic composition according to claim 18 wherein said metabolically impaired mutant is a siderophore mutant.

20. The immunogenic composition according to claim 19 wherein said siderophore is a mycobactin or an exochelin.

21. The immunogenic composition according to claim 18 wherein said growth regulatable rBCG is an auxotroph and wherein tryptophan, glutamine or pantothenic acid is used to regulate growth of said auxotroph.

22. The immunogenic composition according to claim 21 wherein tryptophan is used to regulate growth of said auxotroph.

23. The immunogenic composition according to claim 21 wherein glutamine is used to regulate growth of said auxotroph.

24. The immunogenic composition according to claim 21 wherein pantothenic acid is used to regulate growth of said auxotroph.

25. The immunogenic composition according to claim 18 wherein said growth regulatable rBCG is a prototroph.

26. An immunogenic composition comprising a rBCG having an extrachromosomal nucleic acid sequence comprising a gene encoding for a Mycobacteria major extracellular protein selected from the group consisting of 30 kDa, 23.5 kDa, 32 kDa and combinations thereof, wherein said Mycobacteria major extracellular proteins are over expressed and secreted;

wherein said rBCG is an auxotroph; and

wherein pantothenic acid is used to regulate growth of said auxotroph.

27. A vaccine strategy comprising:

administering a first immunogenic composition to a vaccinee wherein said first immunogenic composition is a BCG;

administering a second immunogenic composition to said vaccinee optionally in the presence of an adjuvant, wherein said second immunogenic composition is a purified Mycobacteria major extracellular protein; and

wherein a protective immune response results in said vaccinee.

28. The vaccine strategy according to claim 27 wherein said BCG is a rBCG that over expresses a Mycobacteria major extracellular protein.

29. The vaccine strategy according to either of claims 27 or 28 wherein said Mycobacteria major extracellular protein is derived from a *Mycobacterium* selected from the group consisting of *Mycobacterium tuberculosis* (Mtb), *Mycobacterium bovis* (MB), and *Mycobacterium leprae* (ML).

30. The vaccine strategy according to claim 27 wherein said purified Mycobacteria major extracellular protein is a purified recombinant Mycobacteria major extracellular protein.

31. The vaccine strategy according to claim 27 wherein said purified Mycobacteria major extracellular protein is selected from the group consisting of Mtb 23.5 kDa protein, Mtb 30 kDa protein, Mtb 32A kDa protein, MB 30 kDa protein, MB 32A kDa protein, ML 23.5 kDa protein, ML 30 kDa protein and ML 32A kDa protein.

32. The vaccine strategy according to claim 28 wherein said rBCG over expresses a Mycobacteria major extracellular protein selected from the group consisting of Mtb 23.5 kDa protein, Mtb 30 kDa protein, Mtb 32A kDa protein, MB 30

kDa protein, MB 32A kDa protein, ML 23.5 kDa protein, ML 30 kDa protein and ML 32A kDa protein.

33. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is Mtb 23.5 kDa protein.

34. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is Mtb 30 kDa protein.

35. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is Mtb 32A kDa protein.

36. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is MB 30 kDa protein.

36. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is MB 32A kDa protein.

37. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is ML 23.5 kDa protein.

38. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is ML 30 kDa protein.

39. The vaccine strategy according to either of claims 31 or 32 wherein said Mycobacteria major extracellular protein is ML 32A kDa protein.

40. The vaccine strategy according to claim 28 wherein said Mycobacterial major extracellular protein and said purified Mycobacterial major extracellular protein are the same protein.

41. A vaccine strategy comprising:

administering a first immunogenic composition to a vaccine wherein said first immunogenic composition is BCG;

administering a second immunogenic composition to said vaccine wherein said second immunogenic composition is purified *Mycobacterium tuberculosis* 30 kDa protein; and

wherein a protective immune response results in said vaccine.

42. The vaccine strategy according to claim 41 further comprising an adjuvant.